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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend title XI of the Social Security Act to expand the drug price negotiation program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M_____. _____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend title XI of the Social Security Act to expand the drug price negotiation program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lowering Drug Costs
5 for American Families Act”.

6 **SEC. 2. EXPANDING THE DRUG PRICE NEGOTIATION PRO-**
7 **GRAM.**

8 (a) INCREASING THE NUMBER OF DRUGS SUBJECT
9 TO NEGOTIATION.—Section 1192(a)(4) of the Social Se-

1 security Act (42 U.S.C. 1320f–1(a)(4)) is amended by strik-
2 ing “20” each place it appears and inserting “50” in each
3 such place.

4 (b) EXPANSION OF DEFINITION OF MAXIMUM FAIR
5 PRICE ELIGIBLE INDIVIDUAL.—Section 1191(c)(2) of the
6 Social Security Act (42 U.S.C. 1320f–1(c)(2)) is amend-
7 ed—

8 (1) in subparagraph (A), by inserting “, or a
9 participant, beneficiary, or enrollee who is enrolled
10 under a group health plan or health insurance cov-
11 erage offered in the group or individual market (as
12 such terms are defined in section 2791 of the Public
13 Health Service Act) with respect to which there is in
14 effect an agreement with the Secretary under section
15 1197 with respect to such selected drug as so fur-
16 nished or dispensed” after “such selected drug”; and

17 (2) in subparagraph (B), by inserting “, or a
18 participant, beneficiary, or enrollee who is enrolled
19 under a group health plan or health insurance cov-
20 erage offered in the group or individual market (as
21 such terms are defined in section 2791 of the Public
22 Health Service Act) with respect to which there is in
23 effect an agreement with the Secretary under section
24 1197 with respect to such selected drug as so fur-
25 nished or administered” after “such selected drug”.

1 (c) APPLICATION OF ADMINISTRATIVE PROCEDURES
2 TO NEW MAXIMUM FAIR PRICE ELIGIBLE INDIVID-
3 UALS.—Section 1196(a)(3) of the Social Security Act (42
4 U.S.C. 1320f–5(a)(3)) is amended—

5 (1) in subparagraph (A), by striking “and” at
6 the end;

7 (2) in subparagraph (B), by striking the period
8 and inserting “; and”; and

9 (3) by adding at the end the following new sub-
10 paragraph:

11 “(C) maximum fair price eligible individ-
12 uals not described in subparagraph (A) or
13 (B).”.

14 (d) HEALTH INSURER AGREEMENTS.—Part E of
15 title XI of the Social Security Act (42 U.S.C. 1320f et
16 seq.) is amended—

17 (1) by redesignating sections 1197 and 1198 as
18 sections 1198 and 1199, respectively; and

19 (2) by inserting after section 1196 the following
20 new section:

21 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
22 **HEALTH PLANS.**

23 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-
24 GRAM.—

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 under the program under this part the Secretary
3 shall be treated as having in effect an agreement
4 with a group health plan or health insurance issuer
5 offering group or individual health insurance cov-
6 erage (as such terms are defined in section 2791 of
7 the Public Health Service Act), with respect to a
8 price applicability period and a selected drug with
9 respect to such period—

10 “(A) in the case such selected drug fur-
11 nished or dispensed at a pharmacy or by mail
12 order service if coverage is provided under such
13 plan or coverage during such period for such se-
14 lected drug as so furnished or dispensed; and

15 “(B) in the case such selected drug fur-
16 nished or administered by a hospital, physician,
17 or other provider of services or supplier if cov-
18 erage is provided under such plan or coverage
19 during such period for such selected drug as so
20 furnished or administered.

21 “(2) OPTING OUT OF AGREEMENT.—The Sec-
22 retary shall not be treated as having in effect an
23 agreement under the program under this part with
24 a group health plan or health insurance issuer offer-
25 ing group or individual health insurance coverage

1 with respect to a price applicability period and a se-
2 lected drug with respect to such period if such a
3 plan or issuer affirmatively elects, through a process
4 specified by the Secretary, not to participate under
5 the program with respect to such period and drug.

6 “(b) PUBLICATION OF ELECTION.—With respect to
7 each price applicability period and each selected drug with
8 respect to such period, the Secretary and the Secretary
9 of Labor and the Secretary of the Treasury, as applicable,
10 shall make public a list of each group health plan and each
11 health insurance issuer offering group or individual health
12 insurance coverage, with respect to which coverage is pro-
13 vided under such plan or coverage for such drug, that has
14 elected under subsection (a) not to participate under the
15 program with respect to such period and drug.”.

16 (e) APPLICATION TO GROUP HEALTH PLANS AND
17 HEALTH INSURANCE COVERAGE.—

18 (1) PHSA.—Part D of title XXVII of the Pub-
19 lic Health Service Act (42 U.S.C. 300gg–111 et
20 seq.) is amended by adding at the end the following
21 new section:

22 **“SEC. 2799A–11. DRUG PRICE NEGOTIATION PROGRAM AND**
23 **APPLICATION OF MAXIMUM FAIR PRICES.**

24 “(a) IN GENERAL.—In the case of a group health
25 plan or health insurance issuer offering group or indi-

1 vidual health insurance coverage that is treated under sec-
2 tion 1197 of the Social Security Act as having in effect
3 an agreement with the Secretary under the Drug Price
4 Negotiation Program under part E of title XI of such Act,
5 with respect to a price applicability period (as defined in
6 section 1191(b) of such Act) and a selected drug (as de-
7 fined in section 1192(c) of such Act) with respect to such
8 period for which coverage is provided under such plan or
9 coverage—

10 “(1) the provisions of such part shall apply—

11 “(A) in the case the drug is furnished or
12 dispensed at a pharmacy or by a mail order
13 service, to such plan or coverage, and to the
14 participants, beneficiaries, and enrollees en-
15 rolled under such plan or coverage, during such
16 period, with respect to such selected drug, in
17 the same manner as such provisions apply to
18 prescription drug plans and MA–PD plans, and
19 to participants, beneficiaries, and enrollees en-
20 rolled under such prescription drug plans and
21 MA–PD plans during such period; and

22 “(B) in the case the drug is furnished or
23 administered by a hospital, physician, or other
24 provider of services or supplier, to such plan or
25 coverage, and to the participants, beneficiaries,

1 and enrollees enrolled under such plan or cov-
2 erage, and to hospitals, physicians, and other
3 providers of services and suppliers during such
4 period, with respect to such drug in the same
5 manner as such provisions apply to the Sec-
6 retary, to participants, beneficiaries, and enroll-
7 ees entitled to benefits under part A of title
8 XVIII or enrolled under part B of such title,
9 and to hospitals, physicians, and other pro-
10 viders and suppliers participating under title
11 XVIII during such period;

12 “(2) the plan or issuer shall apply any cost-
13 sharing responsibilities under such plan or coverage,
14 with respect to such selected drug, by substituting
15 an amount not more than the maximum fair price
16 negotiated under such part E of title XI for such
17 drug in lieu of the drug price upon which the cost-
18 sharing would have otherwise applied, and such cost-
19 sharing responsibilities with respect to such selected
20 drug may not exceed such maximum fair price; and

21 “(3) the Secretary shall apply the provisions of
22 such part E to such plan, issuer, and coverage, such
23 participants, beneficiaries, and enrollees so enrolled
24 in such plans and coverage, and such hospitals, phy-

1 sicians, and other providers and suppliers partici-
2 pating in such plans and coverage.

3 “(b) NOTIFICATION REGARDING NONPARTICIPATION
4 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
5 health plan or a health insurance issuer offering group or
6 individual health insurance coverage shall publicly dis-
7 close, in a manner and in accordance with a process speci-
8 fied by the Secretary, any election made under section
9 1197 of the Social Security Act by such plan or issuer
10 to not participate in the Drug Price Negotiation Program
11 under part E of title XI of such Act with respect to a
12 selected drug (as defined in section 1192(c) of such Act)
13 for which coverage is provided under such plan or coverage
14 before the beginning of the plan year for which such elec-
15 tion was made.”.

16 (2) ERISA.—

17 (A) IN GENERAL.—Subpart B of part 7 of
18 subtitle B of title I of the Employee Retirement
19 Income Security Act of 1974 (29 U.S.C. 1181
20 et seq.) is amended by adding at the end the
21 following new section:

22 **“SEC. 726. DRUG PRICE NEGOTIATION PROGRAM AND AP-
23 PLICATION OF MAXIMUM FAIR PRICES.**

24 “(a) IN GENERAL.—In the case of a group health
25 plan or health insurance issuer offering group health in-

1 surance coverage that is treated under section 1197 of the
2 Social Security Act as having in effect an agreement with
3 the Secretary of Health and Human Services under the
4 Drug Price Negotiation Program under part E of title XI
5 of such Act, with respect to a price applicability period
6 (as defined in section 1191(b) of such Act) and a selected
7 drug (as defined in section 1192(c) of such Act) with re-
8 spect to such period for which coverage is provided under
9 such plan or coverage—

10 “(1) the provisions of such part shall apply, as
11 applicable—

12 “(A) in the case the drug is furnished or
13 dispensed at a pharmacy or by a mail order
14 service, to such plan or coverage, and to the
15 participants and beneficiaries enrolled under
16 such plan or coverage, during such period, with
17 respect to such selected drug, in the same man-
18 ner as such provisions apply to prescription
19 drug plans and MA–PD plans, and to partici-
20 pants and beneficiaries enrolled under such pre-
21 scription drug plans and MA–PD plans during
22 such period; and

23 “(B) in the case the drug is furnished or
24 administered by a hospital, physician, or other
25 provider of services or supplier, to the group

1 health plan or coverage offered by an issuer, to
2 the participants and beneficiaries enrolled
3 under such plans or coverage, and to hospitals,
4 physicians, and other providers of services and
5 suppliers during such period, with respect to
6 such drug in the same manner as such provi-
7 sions apply to the Secretary of Health and
8 Human Services, to participants and bene-
9 ficiaries entitled to benefits under part A of
10 title XVIII or enrolled under part B of such
11 title, and to hospitals, physicians, and other
12 providers and suppliers participating under title
13 XVIII during such period;

14 “(2) the plan or issuer shall apply any cost-
15 sharing responsibilities under such plan or coverage,
16 with respect to such selected drug, by substituting
17 an amount not more than the maximum fair price
18 negotiated under such part E of title XI for such
19 drug in lieu of the drug price upon which the cost-
20 sharing would have otherwise applied, and such cost-
21 sharing responsibilities with respect to such selected
22 drug may not exceed such maximum fair price; and

23 “(3) the Secretary shall apply the provisions of
24 such part E to such plan, issuer, and coverage, and

1 such participants and beneficiaries so enrolled in
2 such plans.

3 “(b) NOTIFICATION REGARDING NONPARTICIPATION
4 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
5 health plan or a health insurance issuer offering group
6 health insurance coverage shall publicly disclose in a man-
7 ner and in accordance with a process specified by the Sec-
8 retary any election made under section 1197 of the Social
9 Security Act by the plan or issuer to not participate in
10 the Drug Price Negotiation Program under part E of title
11 XI of such Act with respect to a selected drug (as defined
12 in section 1192(c) of such Act) for which coverage is pro-
13 vided under such plan or coverage before the beginning
14 of the plan year for which such election was made.”.

15 (B) APPLICATION TO RETIREE AND CER-
16 TAIN SMALL GROUP HEALTH PLANS.—Section
17 732(a) of the Employee Retirement Income Se-
18 curity Act of 1974 (29 U.S.C. 1191a(a)) is
19 amended by striking “section 711” and insert-
20 ing “sections 711 and 726”.

21 (C) CLERICAL AMENDMENT.—The table of
22 sections for subpart B of part 7 of subtitle B
23 of title I of the Employee Retirement Income
24 Security Act of 1974 is amended by adding at
25 the end the following:

“Sec. 726. Drug Price Negotiation Program and application of maximum fair prices.”.

1 (3) IRC.—

2 (A) IN GENERAL.—Subchapter B of chap-
3 ter 100 of the Internal Revenue Code of 1986
4 is amended by adding at the end the following
5 new section:

6 **“SEC. 9826. DRUG PRICE NEGOTIATION PROGRAM AND AP-**
7 **PLICATION OF MAXIMUM FAIR PRICES.**

8 “(a) IN GENERAL.—In the case of a group health
9 plan that is treated under section 1197 of the Social Secu-
10 rity Act as having in effect an agreement with the Sec-
11 retary of Health and Human Services under the Drug
12 Price Negotiation Program under part E of title XI of
13 such Act, with respect to a price applicability period (as
14 defined in section 1191(b) of such Act) and a selected
15 drug (as defined in section 1192(c) of such Act) with re-
16 spect to such period for which coverage is provided under
17 such plan—

18 “(1) the provisions of such part shall apply, as
19 applicable—

20 “(A) if coverage of such selected drug is
21 provided under such plan if the drug is fur-
22 nished or dispensed at a pharmacy or by a mail
23 order service, to the plan, and to the partici-
24 pants and beneficiaries enrolled under such

1 plan during such period, with respect to such
2 selected drug, in the same manner as such pro-
3 visions apply to prescription drug plans and
4 MA-PD plans, and to participants and bene-
5 ficiaries enrolled under such prescription drug
6 plans and MA-PD plans during such period;
7 and

8 “(B) if coverage of such selected drug is
9 provided under such plan if the drug is fur-
10 nished or administered by a hospital, physician,
11 or other provider of services or supplier, to the
12 plan, to the participants and beneficiaries en-
13 rolled under such plan, and to hospitals, physi-
14 cians, and other providers of services and sup-
15 pliers during such period, with respect to such
16 drug in the same manner as such provisions
17 apply to the Secretary of Health and Human
18 Services, to participants and beneficiaries enti-
19 tled to benefits under part A of title XVIII or
20 enrolled under part B of such title, and to hos-
21 pitals, physicians, and other providers and sup-
22 pliers participating under title XVIII during
23 such period;

24 “(2) the plan shall apply any cost-sharing re-
25 sponsibilities under such plan, with respect to such

1 selected drug, by substituting an amount not more
2 than the maximum fair price negotiated under such
3 part E of title XI for such drug in lieu of the drug
4 price upon which the cost-sharing would have other-
5 wise applied, and such cost-sharing responsibilities
6 with respect to such selected drug may not exceed
7 such maximum fair price; and

8 “(3) the Secretary shall apply the provisions of
9 such part E to such plan and such participants and
10 beneficiaries so enrolled in such plan.

11 “(b) NOTIFICATION REGARDING NONPARTICIPATION
12 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
13 health plan shall publicly disclose in a manner and in ac-
14 cordance with a process specified by the Secretary any
15 election made under section 1197 of the Social Security
16 Act by the plan to not participate in the Drug Price Nego-
17 tiation Program under part E of title XI of such Act with
18 respect to a selected drug (as defined in section 1192(c)
19 of such Act) for which coverage is provided under such
20 plan before the beginning of the plan year for which such
21 election was made.”.

22 (B) APPLICATION TO RETIREE AND CER-
23 TAIN SMALL GROUP HEALTH PLANS.—Section
24 9831(a)(2) of the Internal Revenue Code of
25 1986 is amended by inserting “other than with

1 respect to section 9826,” before “any group
2 health plan”.

3 (C) CLERICAL AMENDMENT.—The table of
4 sections for subchapter B of chapter 100 of
5 such Code is amended by adding at the end the
6 following new item:

“Sec. 9826. Drug Price Negotiation Program and application of maximum fair
prices.”.

7 **SEC. 3. APPLICATION OF PRESCRIPTION DRUG INFLATION**
8 **REBATES TO DRUGS FURNISHED IN THE**
9 **COMMERCIAL MARKET.**

10 (a) PART B DRUGS.—

11 (1) APPLICATION OF PRESCRIPTION DRUG IN-
12 FLATION REBATES TO DRUGS FURNISHED IN THE
13 COMMERCIAL MARKET.—Section 1847A(i) of the So-
14 cial Security Act (42 U.S.C. 1395w–3a(i)) is amend-
15 ed—

16 (A) in paragraph (1)(A)(i), by striking
17 “units” and inserting “billing units”;

18 (B) in paragraph (2)(A), by striking “for
19 which payment is made under this part” and
20 inserting “that would be payable under this
21 part if such drug were furnished to an indi-
22 vidual enrolled under this part”;

23 (C) in paragraph (3)—

1 (i) in subparagraph (A)(i), by striking
2 “units” and inserting “billing units”; and
3 (ii) by striking subparagraph (B) and
4 inserting the following:

5 “(B) TOTAL NUMBER OF BILLING
6 UNITS.—For purposes of subparagraph (A)(i),
7 the total number of billing units with respect to
8 a part B rebatable drug is determined as fol-
9 lows:

10 “(i) Determine the total number of
11 units equal to—

12 “(I) the total number of units, as
13 reported under subsection (c)(1)(B)
14 for each National Drug Code of such
15 drug during the calendar quarter that
16 is two calendar quarters prior to the
17 calendar quarter as described in sub-
18 paragraph (A), minus

19 “(II) the total number of units
20 with respect to each National Drug
21 Code of such drug for which payment
22 was made under a State plan under
23 title XIX (or waiver of such plan), as
24 reported by States under section
25 1927(b)(2)(A) for the rebate period

1 that is the same calendar quarter as
2 described in subclause (I).

3 “(ii) Convert the units determined
4 under clause (i) to billing units for the bill-
5 ing and payment code of such drug, using
6 a methodology similar to the methodology
7 used under this section, by dividing the
8 units determined under clause (i) for each
9 National Drug Code of such drug by the
10 billing unit for the billing and payment
11 code of such drug.

12 “(iii) Compute the sum of the billing
13 units for each National Drug Code of such
14 drug in clause (ii).”.

15 (2) EFFECTIVE DATE.—The amendments made
16 by this subsection shall apply with respect to cal-
17 endar quarters beginning after the date of the enact-
18 ment of this Act.

19 (b) COVERED PART D DRUGS.—

20 (1) APPLICATION OF PRESCRIPTION DRUG IN-
21 FLATION REBATES TO DRUGS FURNISHED IN THE
22 COMMERCIAL MARKET.—Section 1860D–14B of the
23 Social Security Act (42 U.S.C. 1395w–114b) is
24 amended—

25 (A) in subsection (b)—

1 (i) in paragraph (1)—

2 (I) in subparagraph (A)(i), by
3 striking “the total number of units”
4 and all that follows through the semi-
5 colon and inserting the following: “the
6 total number of units that are used to
7 calculate the average manufacturer
8 price of such dosage form and
9 strength with respect to such part D
10 rebatable drug, as reported by the
11 manufacturer of such drug under sec-
12 tion 1927 for each month, with re-
13 spect to such period;”; and

14 (II) by striking subparagraph (B)
15 and inserting the following:

16 “(B) EXCLUDED UNITS.—For purposes of
17 subparagraph (A)(i), the Secretary shall exclude
18 from the total number of units for a dosage
19 form and strength with respect to a part D
20 rebatable drug, with respect to an applicable pe-
21 riod, the following:

22 “(i) Units of each dosage form and
23 strength of such part D rebatable drug for
24 which payment was made under a State
25 plan under title XIX (or waiver of such

1 plan), as reported by States under section
2 1927(b)(2)(A).

3 “(ii) Units of each dosage form and
4 strength of such part D rebatable drug for
5 which a rebate is paid under section
6 1847A(i).

7 “(iii) Beginning with plan year 2026,
8 units of each dosage form and strength of
9 such part D rebatable drug for which the
10 manufacturer provides a discount under
11 the program under section 340B of the
12 Public Health Service Act.”; and

13 (ii) in paragraph (6), by striking “IN-
14 FORMATION.—The Secretary” and all that
15 follows through “rebatable covered part D
16 drug dispensed” and inserting the fol-
17 lowing: “AMP REPORTS.—The Secretary
18 shall provide for a method and process
19 under which, in the case of a manufacturer
20 of a part D rebatable drug that submits
21 revisions to information submitted under
22 section 1927 by the manufacturer with re-
23 spect to such drug”; and

24 (B) by striking subsection (d) and insert-
25 ing the following:

1 “(d) INFORMATION.—For purposes of carrying out
2 this section, the Secretary shall use information submitted
3 by manufacturers under section 1927(b)(3) and informa-
4 tion submitted by States under section 1927(b)(2)(A).”.

5 (2) EFFECTIVE DATE.—The amendments made
6 by this subsection shall apply with respect to appli-
7 cable periods (as defined in section 1860D–
8 14B(g)(7) of the Social Security Act (42 U.S.C.
9 1395w–114b(g)(7))) beginning after the date of the
10 enactment of this Act.